K030140

XIII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Separate Page)

A. Submitter: Charles Kokinos, DuoMed, Inc., 400 North Point Pkwy., West Palm Beach, FL 33407. Phone 561-686-2619.

I. Classification: Class II.

MAR 1 8 2003

II. Common or usual name: TENS Device

III. Proprietary Name: DuoMed™, 500 Series

IV. Registration No.: In process

V. Classification Name: Transcutaneous Electrical Nerve Stimulator, Class II, Code GZJ.

VI. Performance standards: No mandatory standards applicable.

VII. Description: The DuoMed™ Series 500 is a non-invasive nerve stimulation therapy device, indicated for use in treatment of symptomatic relief of and management of long-term intractable pain and/or as an adjunctive treatment in the management of post-surgical or post-traumatic pain. It has an adjustable pulse amplitude, pulse rate, and pulse width, with an automatic modulation mode for the pulse width. It can be used in "normal" modes,"burst" mode or in "modulation" mode following the directions of the prescribing physician. Like the Graham-Field (and several other) devices it operates with a 9 V alkaline or nickel-cadmium rechargeable battery.

VIII. Labels and Labeling: Labels and labeling are provided including labels of competitive products.

IX. Substantial Equivalence: It is equivalent to several devices but especially to the Graham-Field TENS Plus device cleared under K924876, and the Yoram device cleared under K002297 to which it is nearly identical.

The "510(k) Substantial Equivalence Decision-making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed and the Decision tree is shown in Attachment V.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2003

Mr. Charles Kokinos
President
Duomed, Inc.
400 Northpoint Parkway, #406
West Palm Beach, FL 33407

Re: K030140
Trade/Device Name: DuoMed™ Series 500, (Models ID 500, FL 500)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: January 3, 2003
Received: January 14, 2003

Dear Mr. Kokinos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

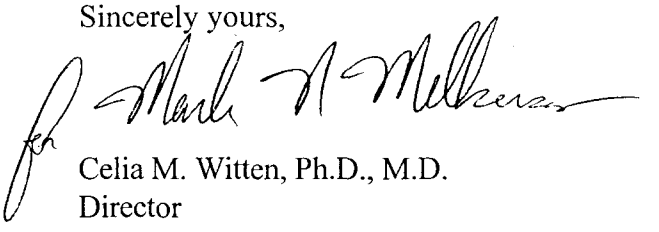
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:

Device Name: DuoMed™, Series 200 (Model T-202)

Indications for Use:

Indicated for the symptomatic relief and management of chronic (long term) intractable pain and/or as an adjunct treatment in the management of post-surgical and post-traumatic acute pain.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ or Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K030140